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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,802	02/12/2004	Sheng-Ping (Samuel) Zhong	03-235	5369
27774 MAYER & WI	7590 12/02/200 LLIAMS PC	EXAMINER		
251 NORTH A	·	AHMED, HASAN SYED		
2ND FLOOR WESTFIELD, I	NJ 07090	ART UNIT	PAPER NUMBER	
			1615	
			MAIL DATE	DELIVERY MODE
			12/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary 19/777,802			Appl	ication No.	Applicant(s)			
HASAN S. AHMED 1615	Office Action Summary		10/7	77,802	ZHONG, SHENG-PING (SAMUEL)			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address → Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Betweensor to term may be evaluate under the provision of 3° CFR 1360. Inne event, however, may any by the timely filed If NO period for right is squedied above, the maximum statutory instead val apply and oil despite SIX (8) MONTHS from the mating date of this communication. Faller be reply which like set of selected period for right is quadred path of the communication. Period for right is quadred path of this communicat			Exan	niner	Art Unit			
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DETAILED ACTION

Receipt is acknowledged of applicant's amendment and response, which were filed

on 12 September 2008.

• The 35 USC 112 rejection of the previous Office action is withdrawn in view of the

amendment.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 September 2008 has been entered.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2, 17-19, 21-23, and 25 remain rejected under 35 U.S.C. 102(a) as being anticipated by WO 2003/026532 ("Weber").

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Weber discloses a medical article comprising a release region (see page 2, lines 22-28), further comprising:

 the polymeric carrier comprising a first polymer of instant claim 1 (see page 8, lines 5-15);

- the drug loaded nanoparticles dispersed within the polymeric carrier of instant claim 1 (see page 11, lines 14-16);
- the layered silicate material (phyllosilicate) of instant claim 1 (see page 9, line
 4);
- the hydrophilic therapeutic agent of instant claim 2 (see page 11, line 17 page 12, line 6; e.g. acetylsalicylic acid);
- the hydrophobic polymer of instant claim 2 (see page 8, lines 5-15; e.g. polyolefin block copolymer);
- the disposal over at least a portion of the medical article substrate of instant claim 17 (see figure 1);
- the coronary or peripheral vasculature implantable or insertable medical device of instant claim 19 (see page 20, lines 16-21);
- the catheter of instant claim 21 (see page 20, line 19);
- the antithrombotic agent of instant claim 22 (see page 11, line 18);
- the smectite silicate material of instant claim 23 (see page 9, line 4); and
- the method of instant claim 25 (see page 6, lines 3-15).

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 3 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Weber in view of U.S. Application No. 2005/0149175 ("Hunter").

Weber teaches a medical article comprising a release region (*see* above). The disclosed article comprises the polyolefin-polyvinylaromatic block copolymer of instant claim 3 (*see* page 8, lines 5-15).

Weber explains that the disclosed invention, "...advantageously provides the opportunity to provide a variation in one or more properties within one or more dimensions of the inventive device than can be achieved in medical devices not comprising nanomaterials." See page 18, lines 25-27.

Weber differs from the instant application in that it does not teach halofuginone as a therapeutic agent. However, use of halofuginone as a therapeutic agent in vascular medical devices was well known in the art at the time the instant application was filed, as evinced by Hunter (see paragraph 0415).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a vascular medical device comprising a release region, further comprising a polymeric carrier and nanoparticles comprising halofuginone, as taught by Weber in view of Hunter. One of ordinary skill in the art at the time the

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invention was made would have been motivated to make such a composition because it provides more flexibility in properties than medical devices not comprising nanomaterials, as explained by Weber.

* * * * *

Response to Arguments

Applicant's arguments filed on 12 September 2008 have been fully considered but they are not persuasive.

35 USC 102(a)

Applicant argues that, "...there is no instruction or enabling disclosure in Weber for incorporating a therapeutic agent into a layered silicate material to create the claimed nanoparticle structure..." See remarks, pages 7-8.

Examiner respectfully submits that like applicant, Weber discloses drug loaded nanoparticles (see page 11, lines 14-16). Like applicant, Weber's nanoparticles may comprise layered silicate (phyllosilicate) material (see page 9, line 4). Like applicant, Weber discloses a hydrophilic therapeutic agent (see page 11, line 17 – page 12, line 6) and a hydrophobic polymer (see page 8, lines 5-15). Like applicant, Weber discloses layered silicate material comprising smectite (see page 6, lines 3-15).

Since Weber uses the silicate nanoparticles made of the same material as recited in the instant application and associates those nanoparticles with the same therapeutic agents as recited in the instant application, examiner respectfully submits that Weber's therapeutic agent will inherently associate with Weber's silicate nanoparticles in the manner recited in instant claim 1 and will inherently form the depot

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of instant claim 1. As explained in the instant application (see, e.g., paragraph 0033), Weber's therapeutic agent and Weber's layered silicate may both be hydrophilic or hydrophobic, causing spontaneous association of the therapeutic agent with the layered silicate in the manner recited in instant claim 1. As such, examiner respectfully submits that Weber anticipates the instant application as claimed.

* * *

35 USC 103(a)

Applicant argues that the obviousness rejection fails because Weber does not anticipate instant claim 1. See remarks, pages 8-9.

As explained above and contrary to applicant's assertion, it is examiner's position that Weber anticipates instant claim 1.

 *

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./ Examiner, Art Unit 1615

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615